REMARKS

This application has been reviewed in light of the Advisory Action dated January 12, 2010. Claims 46-59 and 65-90 are presented for examination, of which claim 46 is in independent form. Claim 46 has been amended to more clearly define the intended invention. Support for the amendment may be found in original claim 1 and on page 5, lines 12-17 of the subject specification as filed, International Publication No. WO 2005/053578 ("the '578 publication"). No new matter has been added. Favorable reconsideration is respectfully requested.

Claims 46-59 and 65-90 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,626,950 B2 to Brown et al. (Brown) in view of U.S. Patent No. 5,141,510 to Takagi et al. (Takagi). Applicants respectfully traverse this rejection in view of the following remarks.

The present invention is directed to a triphasic prosthetic device having a base component that is comprised of a synthetic ceramic that can be anchored in or onto an osteochondrial environment. The independent claim makes clear that at least 50% of the highly oriented hollow bodies of the polymeric hollow body component are aligned essentially parallel to the insertion axis of the prosthetic device. Whereas previously known prosthetic articular cartilage devices have been unstable leading to the need for replacement by another surgical operation, the presently claimed device provides a prosthetic articular cartilage material which has an improved structural stability and provides for accurate positioning in the bone. In addition, the device of this invention is made of materials that are biomechanically able to withstand normal joint forces and to promote repair and replacement of cartilage tissue or

cartilage-like tissue. It is respectfully submitted that the advantageous device of the present invention is not disclosed or suggested by the prior art of record.

Brown describes an implantable device comprising a foamed polymer (scaffold) and a ceramic base component (column 3, lines 13 to 22). The polymeric part of this implant is a porous polymer produced in a foaming process (column 5, lines 40 to 57). Further, it is generally described in column 4, lines 8 to 11, that the polymer may have channels that run through the porous polymer foam for improved cell invasion, vascularization and nutrient diffusion.

The Examiner states that without Applicants providing further clarification of the plane and articulating surface of the base component, as previously recited in claim 46, the obviousness rejection is maintained. In connection therewith, the Examiner alleges that the hollow bodies taught by Brown are shown to be aligned perpendicularly to at least one plane of an articulating surface. Applicants have herein amended claim 46 to provide further clarification of the invention and to further distinguish the claimed invention from the cited art.

As amended herein, claim 46 is directed toward a triphasic prosthetic device comprising a polymeric hollow body component with a number of highly oriented hollow bodies wherein more than 50% of said number of highly oriented hollow bodies of the polymeric hollow body component are aligned essentially parallel to the insertion axis of the prosthetic device. At page 5, last paragraph of the '578 publication, the specification clearly establishes that the stability of the prosthetic device is essentially improved by this number of highly oriented hollow bodies, which are aligned essentially in parallel to the insertion axis of the prosthetic device, i.e., perpendicularly to the plane of the articulating surface. These hollow bodies form a brush-like structure in a direction perpendicular to the base component (see page 7, last paragraph of the '578 publication). In addition, these highly oriented hollow bodies may

change alignment direction and self-organize at the uppermost end of the brush-like structure which can occur under pressure (by the surgeon) after implantation. (See page 8, first paragraph of the '578 publication). Moreover, the instant specification clearly teaches that the greater the percent alignment, the more preferred is the inventive device. The hollow bodies of the prosthetic device must have the highly organized orientation in order to ensure stability of the device when implanted in the defect side in the joint. (See last paragraph of page 5 of the '578 publication stating "[i]t has been surprisingly found that the stability of a prosthetic articular cartridge device can be improved ...".)

While Brown may disclose pores in the polymeric phase, ceramic phase and interphase region of its prosthetic implant, it says nothing of the orientation of the pores in relation to the implant site. Further, to say that it inherently meets the limitation of highly oriented bodies, including hollow bodies oriented parallel to the insertion site, is simply not the law. The Examiner may not arbitrarily choose any orientation to render the prosthetic device of the present invention obvious in view of prior art, which neither specifically disclose nor suggest the presently claimed invention.

According to M.P.E.P. § 2112 (IV), citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient" to render an invention unpatentable. For something to be deemed "inherent," it must result inevitably from following the prior art. Brown fails to recognize or suggest the highly specific orientation of the channels as taught in the subject invention and fails to show any embodiment of an implant having these highly <u>oriented</u> channels. There is no disclosure of specifically oriented hollow bodies, much less a high degree of hollow body alignment taught or

suggested by Brown. Therefore, the highly oriented hollow bodies of the present invention is not "inherent" from any cited art applied.

Further, the present invention recognized a problem in the art and discovered the solution to that problem. If the prior art does not see or identify the problem, then it can not foresee the solution. See MPEP § 2141.02 (III), citing *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969), "a patentable invention may lie in the discovery of the source of a problem. . ." Brown fails to recognize the benefits to the stability and positioning of the prosthetic device achieved by having more than 50% of highly oriented hollow bodies aligned essentially parallel to the insertion axis of the prosthetic device. Therefore, Applicants submit that Brown fails to render the presently claimed invention obvious.

Takagi fails to remedy the deficiencies of Brown. Takagi describes an implantable device for bone based on calcium phosphate only (see abstract). It is explicitly described in column 4, lines 55 to 60 that the structure of the artificial bone for implantation can be applied for insert, fill-up or cover of a defect or removed portion of a living bone. Takagi is not applicable to reparation of cartilage material. Thus, the skilled person would not have considered Takagi when looking for a way to develop a prosthetic device for repairing or replacing cartilage or cartilage-like tissue.

Accordingly, Applicants respectfully submit that the art of record, whether taken alone or together, does not disclose or suggest the presently claimed invention. Therefore, Applicants respectfully request withdrawal of the § 103 rejection.

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration and early passage to issue of the present application.

Applicants' undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,

/Raymond R. Mandra/
Raymond R. Mandra
Attorney for Applicants
Registration No. 34,382

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

FCHS_WS 4877797_1.DOC